How Hospitals Can Meet Premarket Submission Requirements

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Topics

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- Keys to Successful Premarket Submissions
- Baseline Rules
- Premarket Recommendations
- A sample 510(k)
- A sample PMA

Premarket Recap

- Hospitals and third parties reprocessing single use devices must submit premarket submissions to FDA, if needed, per the prioritzation scheme.
- Submissions are due according to the enforcement guidance.
- Submit the documents in the form and manner described this morning.

Keys to Successful Premarket Submissions

- Gather all the relevant public premarket guidance and information on your device.
- Communicate early with FDA if you need clarification, advice, or help.
- Form a competent team with mixed skills to coordinate and complete the process.
- Assess your capabilities and get support if needed.

Success Continued

- Assemble a complete submission that addresses each required element.
- Critique and edit the document before submission.
- Be prepared to respond as quickly as possible to FDA requests for information. Understand what FDA wants before doing anything.

Baseline Rules

- The OEM and reprocessor are subject to the same premarket requirements.
- The reprocessor can claim that the device is either a single use device or a reusable device; test and label it accordingly.

Premarket Recommendations

- Define the device(s) with specifications and tolerances.
- Group devices for each submission to the extent that is technically sound.
- Identify and compare critical specifications to legally marketed devices.
- If there are ANY differences with the OEM device these may be significant.

Recommendations Continued

- Consolidate documentation of common processes Use FDA-recognized standards to the extent possible to optimize a quality process and to minimize submission paperwork
- Labeling should be consistent with the OEM device; may need more information

Recommendations Continued

- If test data are needed then look to published information first expect the need for new test data and factor in what you are prepared to do early on.